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## REMARKS

### I. Amendments

Typographical and grammatical errors have been corrected throughout the specification. This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No amendment of inventorship is necessitated by this amendment.

### II. Discussion of the Objection to the Abstract

The Abstract has been objected to as not describing the present invention. By this amendment, the Abstract (submitted as a separate page) has been modified to reflect the pending claims.

Therefore, Applicants respectfully request withdrawal of the objection to the Abstract.

### III. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph

Claims 1-7, 11 and 27 have been rejected under 35 U.S.C. Sec. 112, first paragraph, as allegedly non-enabled with respect to the recited method.

Applicants respectfully disagree that their invention, as set forth in the pending claims, is not enabled. Applicants would like to draw the Examiner's attention to Example 1, starting on page 34 of the specification. In this example, HbA<sub>1c</sub> (defined on page 32, lines 33-34 as glycosylated hemoglobin) decreased by two percent when an exemplary combination treatment was administered. Therefore, Applicants believe that the aspect of their invention, as set forth in independent method claim 1 is adequately enabled.

no only 1 or  
combo

Claims 2-7, 11 and 27 depend upon claim 1. Applicants assert that the more specific dependent claims are also adequately enabled for the same reason.

Claims 22-26 also depend upon claim 1. Applicants respectfully request that the Examiner indicate why she believes these claims to be adequately enabled, should she choose to maintain her rejection of the other claims which are dependent upon claim 1.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

#### **IV. Discussion of the Rejection of Claim 2 under Judicially-Created Doctrine**

Claim 2 has been rejected on the grounds of allegedly not being drawn to a compound having a common core.

Applicants respectfully disagree that the compounds set forth in claim 2 do not have a common core. Applicants respectfully request that the Examiner consult U.S. Patent Nos. 6,087,384 and 6,110,948, wherein the same formula and substituent choices are recited. Applicants believe that these U.S. patents prove that those skilled in the art recognize compounds of the formula in claim 2 to be of a class, and also that the compounds recited in claim 2 have been found to have a common core by other Examiners.

Therefore Applicants respectfully request the withdrawal of the rejection of claim 2 under the judicially-created doctrine.

#### **V. Discussion of the Rejection of Claim 2 under 35 U.S.C. Sec. 112, Second Paragraph**

Claim 2 has been rejected under 35 U.S.C. Sec. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Examiner has raised a question about the structure when L and M are combined to form a chemical bond.

Applicants have discussed the combination of L and M to form a chemical bond on page 17, lines 1-11, *inter alia*. Moreover, Applicants assert that the partial structure described in claim 2 as  $-C(L)H-C(M)<$  is clearly directed to the structures  $-CH_2-CH<$  (when L and M are both hydrogen) or  $-CH=C<$  (when L and M are combined to form a chemical bond). Applicants believe that one skilled in the art would understand the notation which they have recited in claim 1. Furthermore, the same notation is used in the claims of U.S. Patent Nos. 6,087,384 and 6,110,948, indicating that other Examiners have found this option for L and M in combination to be sufficiently clear.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, second paragraph rejection.

## **VI. Discussion of the Rejection under 35 U.S.C. Sec. 103(a)**

Claims 1-7, 11 and 22-27 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly being unpatentable over EP 0 749 751; Kheir El-Din *et al.* (Egypt J. Pharm. Sci. article, 1988) and Heath *et al.* (Diabetes article, 1999) in view of WO 90/13818. Applicants respectfully traverse the rejection.

A Declaration by Dr. Odaka accompanies this response. This Declaration had been previously submitted in the parent application, and shows evidence of surprising results. In particular, Table 1 shows that that glycosylated hemoglobin (HbA1) showed a far greater decrease when an exemplary anorectic and insulin sensitizer were combined than when either was administered alone. Such a dramatic effect was neither taught nor suggested by a consideration of the combined teachings of the cited references. Applicants assert that the results provided by the Declaration are indicative of non-obviousness of the aspects of the invention set forth in independent claim 1.

Claims 2-7, 11 and 22-27 depend upon claim 1. Applicants assert that the more specific dependent claims are also patentable over the combined teachings of the cited references for the same reason.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection.

## **VII. Discussion of the Rejection for Obviousness-Type Double Patenting**

Claims 1-7, 11 and 22-27 have been rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-19 of U.S. Patent No. 6,329,402<sup>4</sup>. As U.S. Patent No. 6,329,402 is an Eisai patent directed to carboxylic acid derivatives and having only six claims, Applicants assume the Examiner may have cited the patent in error.

Therefore, Applicants respectfully request withdrawal of the rejection for obviousness-type double patenting.

### **VIII. Discussion of the Requirement to Elect a Single Species**

The Examiner has indicated that a single disclosed species of insulin sensitizer and anorectic.

Applicants hereby elect the species of claim 25, wherein the insulin sensitizer is pioglitazone or a salt thereof and the anorectic is sibutramine.

### **IX. Discussion of the Supplemental Information Disclosure Statement**

In the Examiner's comments, she indicated that three references had not yet been considered, as they were not in the parent case file. A Supplemental Information Disclosure Statement citing these same three references, and providing copies thereof, accompanies this response.

Moreover, JP 09 067271 corresponds to EP 0 749 751 and JP 05 148196 corresponds to EP 0 516 349. Applicants note that the Examiner has already signed off on the corresponding European patent applications. Applicants respectfully request consideration and acknowledgement of the Supplemental Information Disclosure Statement.

**X. Conclusion**

Reconsideration of the claims and allowance is requested.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: March 7, 2003

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